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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,470	10/07/2003	David L. Bogert		6661

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DAVID L. BOGERT
2401 W. Southern Ave Lot 21
Tempe, AZ 85282

EXAMINER	
CONLEY, SEAN EVERETT	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 07/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

4

Office Action Summary	**Application No.** 10/679,470	**Applicant(s)** BOGERT, DAVID L.
	Examiner Sean E. Conley	**Art Unit** 1744

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2006*.
2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.
3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 6-8* is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5)☐ Claim(s) _____ is/are allowed.
6)☒ Claim(s) *1,3 and 6-8* is/are rejected.
7)☐ Claim(s) _____ is/are objected to.
8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.
10)☒ The drawing(s) filed on *10/7/2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a)☐ All b)☐ Some * c)☐ None of:
1.☐ Certified copies of the priority documents have been received.
2.☐ Certified copies of the priority documents have been received in Application No. _____.
3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The amendment filed May 3, 2006 has been received and considered for examination. Claims 1, 3, and 6-8 are pending. The cancellation of claims 2, 4, 5, 9, and 10 has rendered the rejections of these claims moot.

Claim Objections

2. Claims 1, 3 and 6-8 are objected to because of the following informalities: Currently, claim 1 does not contain active method steps. Process claims should be composed of a series of steps, each of which should state an operation express in the form of the present participle ("ing"), as for example "heating..." and "cooling...". The examiner suggests the applicant review the format of claim 1 in the cited reference of Mills et al. (U.S. Patent No. 6,482,584 B1). Claims 3 and 6-8 are objected for depending from and including all of the subject matter of claim 1. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1, 3, and 6-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The applicant uses the term "wherein" as the transitional phrase for claims 1, 3, and 6-8 and as a result the scope of the claims is vague and indefinite without the use of proper transitional phrases having legally recognized definitions in scope. "Wherein" has been interpreted to mean "comprising" in examination of the claims. The examiner suggests the applicant review the use of traditional transitional phrases (for example; "comprising", "consisting of", and "consisting essentially of") as indicated in section 2111.03 of the M.P.E.P. Appropriate correction is required.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claim 1 is rejected under 35 U.S.C. 102(a) or 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mills et al. (U.S. Patent No. 6,482,584 B1).

Mills et al. discloses a process for treating tissue implants comprising the step of subjecting an entire tissue implant to sonic energy (sonic energy is audible sound energy which has a frequency range of 20Hz to 20KHz, see the dictionary definition of "sonic" provided by the American Heritage Dictionary and also see the definition of "audio frequency" provided by Wikipedia) in a treatment chamber which is sealed and filled with fluid and tissue implants (see col. 10, lines 1-45; col. 6, lines 49-59; figure 1A; col. 9, lines 5-8). The tissue implant is selected from the group comprising allograft, autograft, and xenograft implants (see col. 5, lines 10-15; col. 7, lines 35-45). The sonic energy is applied to the tissue implants in order to clean, impregnate, and sterilize them prior to packaging and implanting (see col. 6, lines 59-67; col. 10, lines 1-35).

Mills et al. appears to anticipate the claimed range of 20 cycles per second to 9,000 cycles per second as recited in claim 1. In the event that Mills et al. does not teach sufficient specificity with regards to the claimed range, it would have been obvious to one of ordinary skill in the art at the time the invention was made to choose any known audible sonic frequency in order to successfully practice the invention of Mills et al.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mills et al. as applied to claim 1 above, and further in view of Rowe et al. (U.S. Patent No. 6,234,990 B1).

Mills et al. fails to specifically teach a treatment chamber that has attached to it two higher frequency sound producing devices which, between them, produce an audible tartini tone sound, said audible tartini tone sound being the frequency obtained by subtracting one device's higher frequency from the other device's higher frequency.

Rowe et al. discloses methods and devices for application of ultrasound to a small area of skin for enhancing transdermal support. The device includes an ultrasound delivery chamber (12) that contains an ultrasound transducer (20) (see col. 6, lines 35-40). Rowe et al. discloses that the sound or ultrasound can be alternatively produced according to a phenomenon known as "Tartini Tones". Lower frequencies can be produced using much smaller transducers. The method relies on the phenomenon that when two sound or ultrasound waves having different frequencies interact, a third wave is created, having a frequency intermediate between the two (see col. 18, lines 27-38). This reference has been relied upon to teach that it is known to replace a single sound generator with two small transducers to produce an audible tartini sound.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Mills et al. and replace the sonic generator with functionally equivalent viable alternative means such as a sound producing device utilizing "Tartini Tones" which includes using small transducers that provide two sound waves which when they interact, a third wave is created, having a frequency intermediate between the two as taught by Rowe et al. in order to provide much smaller sonic generators as compared to one large generator. Furthermore, it would have been obvious to select the known transducers producing a "Tartini Tone" in place of a single sonic generator based on its suitability and desired characteristics.

6. Claims 6 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mills et al.

Regarding claim 6, Mills et al. discloses a process for treating tissue implants comprising the step of subjecting an entire tissue implant to sonic energy (sonic energy is audible sound energy which has a frequency range of 20Hz to 20KHz, see the dictionary definition of "sonic" provided by the American Heritage Dictionary and also see the definition of "audio frequency" provided by Wikipedia) in a treatment chamber which is sealed and filled with fluid and tissue implants (see col. 10, lines 1-45; col. 6, lines 49-59; figure 1A; col. 9, lines 5-8). The tissue implant is selected from the group comprising allograft, autograft, and xenograft implants (see col. 5, lines 10-15; col. 7, lines 35-45). The sonic energy is applied to the tissue implants in order to clean, impregnate, and sterilize them prior to packaging and implanting (see col. 6, lines 59-67; col. 10, lines 1-35). Mills et al. further discloses that those of ordinary skill in the art are familiar with the process of sonication and the conditions whereby sonic energy may be transferred through a fluid to a workpiece such that efficient cleaning and bacterial or cellular disruption is achieved (see col. 6, lines 53-59).

Mills et al. fails to specifically teach that the walls of the tank are vibrated at a frequency such as to induce resonant harmonic oscillations in a liquid column in the treatment chamber at the first harmonic of the liquid column. However, the frequency required to achieve the first harmonic of the liquid column is a result effective variable which when optimized increases the sound magnitude inside the tank. It has been held that the discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art. In re Boesch, 617 F. 2d 272, 205 USPQ 215 (CCPA 1980). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to optimize the frequency required for the process in order to achieve the maximum sound magnitude inside the treatment tank for efficient treatment of the tissue.

Regarding claim 7, Mills et al. discloses the step of subjecting an entire tissue implant to sonic energy (sonic energy is audible sound energy which has a frequency range of 20Hz to 20KHz, see the dictionary definition of "sonic" provided by the American Heritage Dictionary and also see the definition of "audio frequency" provided by Wikipedia) (see col. 6, lines 49-55). The range of 600 cycles per second to 6000 cycles per second falls within the sonic energy range of 20Hz to 20KHz.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mills et al. as applied to claim 6 above, and further in view of Rowe et al.

Mills et al. fails to specifically teach a treatment chamber that has attached to it two higher frequency sound producing devices which, between them, produce an audible tartini tone sound, said audible tartini tone sound being the frequency obtained by subtracting one device's higher frequency from the other device's higher frequency.

Rowe et al. discloses methods and devices for application of ultrasound to a small area of skin for enhancing transdermal support. The device includes an ultrasound delivery chamber (12) that contains an ultrasound transducer (20) (see col. 6, lines 35-40). Rowe et al. discloses that the sound or ultrasound can be alternatively produced according to a phenomenon known as "Tartini Tones". Lower frequencies can be produced using much smaller transducers. The method relies on the phenomenon that when two sound or ultrasound waves having different frequencies interact, a third wave is created, having a frequency intermediate between the two (see col. 18, lines 27-38). This reference has been relied upon to teach that it is known to replace a single sound generator with two small transducers to produce an audible tartini sound.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the process of Mills et al. and replace the sonic generator with functionally equivalent viable alternative means such as a sound producing device utilizing "Tartini Tones" which includes using small transducers that provide two sound waves which when they interact, a third wave is created, having a frequency intermediate between the two as taught by Rowe et al. in order to provide much smaller sonic generators as compared to one large generator. Furthermore, it would have been obvious to select the known transducers producing a "Tartini Tone" in place of a single sonic generator based on its suitability and desired characteristics.

Response to Arguments

8. Applicant's arguments, see pages 8-14, filed May 3, 2006, with respect to the rejection of claim 1 under 35 U.S.C. 102 (b) have been considered but are moot in view of the new ground(s) of rejection. The applicant has amended claim 1 to narrow the claimed frequency range within the audible sound range. Therefore, the amendment of the claim necessitated a new search and a new ground(s) of rejection since the prior art of Wolfinbarger, Jr. (U.S. Patent No. 5,797,871), relied upon in the previous office action, fails to teach audible sonic energy for treating tissues.

9. Applicant's arguments, see page 7, filed May 3, 2006, with regards to the rejection of claims 6-8 under 35 U.S.C. 112, second paragraph have been fully considered and are persuasive. The rejection of claims 6-8 under 35 U.S.C. 112, second paragraph has been withdrawn.

10. Applicant's arguments, see pages 16-19, filed May 3, 2006, with regards to the rejection of claims 3 and 8 under 35 U.S.C. 103(a) has been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Mills et al. in view of Rowe et al.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the reference of Rowe et al. has been relied upon to teach a functionally equivalent alternative means of generating sonic energy or sound waves in the art of sonic generators. Furthermore, Rowe et al. indicates that it is advantageous to use the phenomenon known as "tartini tones" because it relies upon to very small transducers as opposed to a single much larger transducer. Such an arrangement is advantageous where space is limited.

The fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

11. Applicant's arguments, see pages 10, and 19-22, filed May 3, 2006, with respect to the rejection of claims 6 and 7 under 35 U.S.C. 103(a) has been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Mills et al.

Conclusion

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sean E. Conley whose telephone number is 571-272-8414. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SEC
July 6, 2006

KRISANNE JASTRZAB
PRIMARY EXAMINER